DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 9 2005

Alan Minsk, Esq.
David Hoffman, Esq.
Arnall Golden Gregory LLP
1201 West Peachtree Street
2800 One Atlantic Center
Atlanta, Georgia 30309-3450

Re: Docket No. 2004P-0365/CP1

Dear Messrs. Minsk and Hoffman:

This letter responds to your petition dated August 13, 2004, submitted on behalf of Shire US, Inc. (Shire) asking the Food and Drug Administration (FDA) to (1) refrain from approving any abbreviated new drug application (ANDA) for Agrylin (anagrelide hydrochloride) capsules that fails to include monitoring of the active metabolite 3-hydroxy anagrelide (3-HA) in bioequivalence testing to ensure that exposure to the metabolite is similar to that with Agrylin, and (2) require an ANDA applicant for anagrelide hydrochloride capsules to evaluate bioequivalence by monitoring the active metabolite under both fed and fasting conditions because it appears that food affects a patient's exposure to the parent drug and active metabolite in different ways.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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